FDA Risk Communication Advisory Committee
FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31,
Conference Center (rm. 1503), Silver Spring, MD
November 8-9, 2010
Discussion Topics

Discussion Topics for November 8, 2010

1. During the different stages of an outbreak, what does the public need to know about the FDA investigation process and why?

2. When we can't share information for legitimate reasons about an outbreak investigation, how can we maintain the public's confidence?

3. In the life cycle of an outbreak what kinds of information are vital for FDA to release and when? In what ways does the answer depend on the details of the particular outbreak? How can the Agency prepare for outbreak communication?

4. What can the Agency do in order to earn the public's confidence in its Agency's advice and actions?

5. How should FDA identify and address population groups with distinct information needs during outbreaks?

6. What can FDA do to prepare itself and its publics, so as to earn and maintain public trust during crises?

Discussion Topics for November 9, 2010

1. We don't know how many prescription devices are in use. We do know they come into the home through many ways – hospitals, rehab centers, doc offices, medical distributors, and internet. What measures do we need to have in order to analyze and address the use of prescription devices in the home? Surveys through hospital discharge? Surveys through physicians' offices or through insurance firms?

2. There are emotional, physical, cognitive, and educational factors involved in the home caring for another person (or oneself). What type of communication, if any, should occur between the caregiver/patient and the prescriber of a home-use medical device to ensure that the caregiver or patient can safely use a particular device? Some issues to consider relate to the evidence (or lack thereof) concerning:

- the efficacy of instruments for assessing caregiver/patient mental and physician capacities/abilities
- the efficacy of training and teach-back methods in accomplishing desired outcomes
- the number of steps in following written and oral instructions that people can effectively follow and whether there is a number that will clearly lead to mistakes

- the impact of multiple warnings about using a device and whether a certain number will completely overwhelm the user
- how simple or complex a device can be for it to be operated safety by a non-expert

Devices may or may not be designed to operate outside of a clinical environment, yet they are operating there. Although many devices are more portable and compact, they remain very complex to use.

- To what extent, if at all, can effective communication overcome human factors design limitations?
- What information should be collected or what studies should be done to demonstrate that devices can safely and effectively be used by non-healthcare professional patients and caregivers?
- At what point in device development should these studies be conducted for devices going through an approval review?
- If the devices are already on the market, what kind(s) of information should be collected to demonstrate that they should remain on the market because they can be used safely by patients and caregivers?

4. Home environments are extremely uncontrolled and variable. Many devices were not designed to be used outside of well controlled environments.

What does the existing literature tell us can be done, if anything, to assess and address the various high risk factors in the home environment that patients and caregivers must deal with in making the transition from hospital to home care? How would you address the solution to providing consistent communication and training for the patient to use a medical device in the home? Does existing research suggest

- basic risk communications the caregiver or care recipient should get to prepare for natural disasters or power outages
- the channels by which to provide those communications
- how to address the challenge of how to provide information that is only needed in rare circumstances (for example, during a power outage) but must still be available when needed
- Specific tools or mechanisms, such as checklists or video instruction manuals, that have been shown to be effective in communicating complex information